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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/443,863 11/19/99 PARIKH

I	121-104
EXAMINER	

HM12/0420

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ART UNIT	PAPER NUMBER
KISHORE, G	

DATE MAILED: 1615

04/20/00

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 - month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-10 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-10 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

Art Unit: :1615

## **DETAILED ACTION**

### ***Claim Rejections - 35 U.S.C. § 112***

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

- 2. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

**'may be' in claim 1 is not a positive recitation and thus, renders claim 1 indefinite. Combination of the terms 'substantially' and 'completely' is improper since these two terms have entirely different meaning. 'Completely' refers to 100 % while 'substantially' does not. The distinction between 'unaggregated' and 'unagglomerated' is unclear.**

**The distinction between 'phospholipid' and 'amphipathic surfactant' in claim 2 is unclear. Phospholipids are amphipathic surfactants.**

**Proper Markush expression is 'selected from the group consisting of ' (claim 3). The term, either 'and' OR 'or' should only be used before the last Markush component. There should have been a 'comma' between synthetic polymers and inorganic additives.**

**'Polyol' is misspelt in claim 4.**

Art Unit: :1615

**‘preferably’ and ‘more preferably’ and ‘most preferably’ render claim 9 indefinite since it is unclear whether the limitations following these terms are indeed the limitations.**

***Claim Rejections - 35 U.S.C. § 102***

**3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless --**

**4. Claims 1, 3-4, 6, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kearney (5,631,023).**

**Kearney discloses rapidly disintegrating formulations containing the therapeutic agent, gelatin and xanthan gum (note the abstract, examples and claims).**

**(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.**

**5. Claims 1-4, 6 and 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Green (5,976,577).**

**Green discloses rapidly dispersing oral dosage forms wherein the particles are coated with claimed components, The composition contains, other claimed components (note the abstract, columns 5-8, Examples and claims).**

Art Unit: :1615

*Claim Rejections - 35 U.S.C. § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kearney or Green cited above, further in view of Libby (4,432,975).

Kearney and Green do not teach the inclusion of polyethylene glycol in the formulations. In the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to include polyethylene glycol in the quick disintegrating formulations of Green or Kearney with the expectation of obtaining at least similar results since the reference of Libby shows the common practice in the art of inclusion of this compound in quick disintegrating formulations (note the abstract and col. 3).

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kearney or Green cited above, further in view of Carli (5,164,380).

Kearney and Green do not teach the inclusion of colloidal silica in the formulations. In the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to include colloidal silica in the quick disintegrating formulations of Green or Kearney with the expectation of obtaining at least similar results since the reference of Carli shows

Art Unit: :1615

the common practice in the art of inclusion of this compound in quick disintegrating formulations (note the abstract and Example 4).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

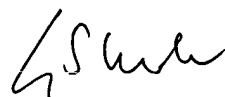
All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Application/Control Number: 09/443,863

Page 6

Art Unit: :1615

**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**



**Gollamudi S. Kishore, Ph. D .**

**Primary Examiner**

**Group 1600**

*gsk*

**April 11, 2000**